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PCT APPLICATION NUMBER: *PCT/US00/15259*

By Authority of the
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)		
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Additional inventors are being named on the ___ sepately numbered sheets attached hereto

TITLE OF THE INVENTION (280 characters max)

MECHANICAL ANASTOMOSIS DELIVERY APPARATUS

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OR

Place Customer Number Bar Code Label here

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ENCLOSED APPLICATION PARTS (*check all that apply*)

X Specification *Number of Pages* 7

X Drawings *Number of Pages* 17

☐ Small Entity Statement

☐ Other (specify)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (*check one*)

X check or money order is enclosed to cover the filing fees

X The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 06-1075

FILING FEE AMOUNT ($): $150.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government

X No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

Date 6/4/99

SIGNATURE Robert R. Jackson

REGISTRATION NO. (*If appropriate*) 26,183

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Docket Number: 293/044 PROV.

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

Descriptive Title of Invention: Mechanical Anastomosis Delivery Apparatus

Description of Invention:

Field of Application: Vascular Interventions

Background:

This invention relates to apparatus for the surgical delivery and deployment of a mechanical anastomosis device (connector). Specifically, the connector is used to provided end to side anastomosis of two vessels. The connector apparatus is a continuation of U.S. patent ("USP") application 09/016,721, case #293/034 and application number 09/187335, case 3293/037. Also disclosed is method and apparatus for creating an aperture for the anastomosis site which is a continuation of USP application 09/014759, case #293/029. In addition, methods and apparatus are disclosed for harvesting an autogenous graft and loading the graft onto a connector and delivery system.

Please note that other connector apparatus (anastomosis devices), not disclosed here, can be used with the apparatus disclosed within this application.

Disclosures:

- An improved mechanical connector (continuation of application number 09/187335, case 293/037)
- A method and apparatus for graft harvesting and loading onto connector and delivery system
  - -Autogenous vein or artery
    - -Graft Transfer Sheath
    - -Graft punch (for attaching graft to connector fingers)
  - -Synthetic graft
- A method and apparatus for creating an aperture for an anastomosis site (USP application 09/014759, case #293/029)
- A method and apparatus for delivery of a mechanical anastomosis device
  - -Autogenous vein or artery
    - -Apparatus
    - -Method/Procedure
  - -Synthetic graft

Drawing Description:

Figure 1 is an illustrative view of the connector

Figure 2 and 3 is an illustrative view of the transfer sheath and delivery system

Figure 4 and 5 is an illustrative view of the VSI aperture forming device and its use

Figure 5b is an alternative embodiment of an aperture-forming device

Figure 5c is an anatomic illustration of the invention: circular cutter apparatus for forming apertures

Figure 6 is an illustrative view of aortic punch prior art.

Figure 7 is an illustrative view of graft pierce tool

Figure 8 is an illustrative view of graft attachment to connector and delivery system

Figure 9 is an illustrative and cross sectional view of connector and delivery system

Figure 10 is an illustrative view of loaded delivery system

Figure 11is an illustrative view of nose cone device and circular cutter

Figure 12 is an illustrative view of delivery; internal finger deployment

Figure 13 is an illustrative view of delivery; external finger deployment

Figure 15 Complete graft and connector delivery system

Figure 16 Anatomic illustration; internal finger connector deployment

Figure 17 Anatomic illustration; external finger connector deployment

Figure 19 Anatomic illustration; completed anastomosis

Figure 20 Anatomic illustration; bypass complete

There is no Figure 14 or Figure 18.

Summary of Invention:

Introduction:

During coronary bypass surgery vein grafts are attached to the ascending aorta (proximal anastomosis) and to the coronary artery (distal anastomosis). The vein graft bypasses the diseased or stenotic region of the coronary artery allowing blood to flow though the graft and perfuse the heart distal to the stenosis site. The proximal anastomosis is achieved by hand sewing or sutureing the vein graft to a hole punched in the aortic artery wall.

Suturing is an effective means for attaching vein grafts. However, the quality of the anastomosis is human dependent in that each anastomosis will be different depending on skill level, experience, [redacted]e and conditions.

With the advent of off-pump coronary artery bypass, where the bypass graft is placed on a beating heart, additional limitations are presented. Specifically, a side-bite or cross clamp is placed on the aorta to pinch enough tissue to allow an anastomosis to be made to the aorta without bleeding. The side-bite clamp introduces significant trauma to the aorta often causing dissections and stroke due to emboli breaking off the interior wall of the aorta.

Vascular Science Inc has developed a new anastomosis device. The device is a mechanical connector designed to attach a saphenous vein graft to the ascending aorta during coronary bypass surgery. The device may also be used with other graft conduits to include arteries and synthetic. Anastomosis sites may be included anywhere in the vascular system including the aorta, and other peripheral arteries. The indication chosen here, for simplicity of illustrating the inventions, is attaching a saphenous vein graft to an aorta. The ancillary devices disclosed here, all devices that support the attachment of the graft and its delivery, are also compatible with any other mechanical anastomosis connector. The aperture-creating device is also compatible with conventional suturing. The mechanical anastomosis device and delivery kit produces an anastomosis equivalent to a hand sewn one, in less time and with minimal training required. An additional advantage of this mechanical anastomosis device is its ability to attach grafts to a pressurized aorta; eliminating the need for side-bite clamping of the aorta. The resulting anastomosis quality is extremely high in that all anastomosis made with this system are perfect in geometry and equivalent. Suturing results in large variability in quality of the geometry and consistency.

The use of the VSI mechanical anstomosis device is provided by an anastomosis connector kit, which includes all components to complete an anastomosis. The kit contains the following components:

- Connector
- Delivery System
- Graft Transfer Sheath
- Graft Punch
- Aortic hole cutter

The Vascular Science Anastomosis device has been developed as an alternative to the current method of suture anastomosis, particularly those connections involving the aorta. The **connector** device consists of a nitinol tube with small "fingers" that extend radially, positioning the device to expand and align the grafted vessel precisely in the center of the precut opening of the primary vessel. The vein graft is harvested per standard procedures and placed on a specialized sheath for transfer onto the delivery system. The **transfer sheath** protects the graft during insertion into the delivery system. The proximal end of the vein graft is secured to the connector device by piercing multiple circumfrentially spaced barbs using a **graft punch tool** provided with the connector kit. During coronary artery bypass procedures, the device is delivered using a system of sliding tubes by which the device, while attached to the vein graft, is passed into the aorta through a hole prepared by a **specialized cutter** also disclosed in this application. The **delivery system** allows the device to become unconstrained on deployment, expanding to firmly attach the graft to the aorta. The delivery system is then removed form the graft. The anastomosis is complete.

Detailed Descriptions:

I. Connector:

The connector is formed from a nickel-titanium (nitinol) tube, which is laser cut into a specific pattern and then formed, by heat setting, in a specific geometry.

Functional performance of the connector is achieved through the following features, see figure 1:

Internal fingers: Engage the internal wall of the aorta to position the connector and graft relative to the aorta. Also aids in mechanical retention of the connector to the aorta.

External fingers: Engage the outside wall of the aorta to position the connector and graft relative to the aorta. Also aids in mechanical retention of the connector to the aorta.

Medial section: Allow the connector to radially expand into the cut hole of the aorta which compresses the graft wall against the cut wall of the aorta producing a hemodynamic seal

Graft Attachment fingers: provide a means for attaching the vein graft to the connector. The fingers are barbed to secure the graft once attached.

II. Graft Harvest and Loading:

The graft is harvested onto a transfer sheath, see figure 2, such that the tapered end of the sheath is inserted into the distal end of the graft. The sheath is then placed onto the delivery system so that the tapered end of the sheath points away from the connector; i.e. the distal graft end becomes the proximal vein graft end to allow valves in vein to be compatible with arterial blood flow. The sheath is then removed while the vein graft is left on the connector delivery tube, see figure 3. The transfer sheath provides a means for inserting the delivery system into the vein graft lumen without compromising the delicate intima of the vein graft. It provides a means for insuring direction of the vein is maintained relative to the connector. Veins have internal valves, which require graft reversal for blood flow when placed in the arterial flow direction. In addition, the transfer sheath is used as a sizing instrument in that a vein graft must accommodate the sheath diameter to be compatible with the connector.

The sheath is made of a low friction, biocompatible polymer such as polyethylene or Polytetrafluoroethylene. The sheath may also be made of metal, i.e. stainless steel.

The size of the sheath is 3mm in diameter. Other sizes are possible, with corresponding connectors, depending on the specific clinical indication of the graft size and desired anastomosis size.

III. Aperture Forming:

A precisely controlled hole and geometry is needed to optimize the performance of the connector. With suturing to the aorta a hole is typically placed in the aorta using an aortic hole punch. A slit is made in the aortic wall, wider then the punch, such that the distal end of the punch can be inserted through the slit into the lumen of the artery. An aortic punch removes a portion of the wall by crushing or forcing an anvil section, inside the artery lumen, against a tube, outside the artery wall, under compression. This compressive action shears and crushes the tissue between the tube and anvil providing an opening in the wall. However, this hole is typically very irregular and variable in size, see figure 6. Also, the initial scalpel slit may be larger then the actual hole which may produce leakage. In addition, surrounding residual tissue, which is left behind, is usually damaged due to the crushing mechanism for removing the section of the wall. This damage can produce a biological healing response for the damaged cells, which can cause inflammation and other adverse events at the critical anastomosis site.

A specialized cutter has been developed to provide a controlled hole in the aorta for creating a mechanical anastomosis. This hole forming method and apparatus may also be used for sutured anastomosis. The object of this new hole forming apparatus is to provide an opening for connecting of a graft which is precisely controlled in size, precisely controlled in geometry, and removes damaged or destroyed cells with the removed plug.

The cutter uses a barbed needle and circular cutter, see figure 4. The needle is placed through the wall of the aorta first. The needle serves as a pilot to guide a cutter through the wall. The needle is barbed to retain the cut tissue plug for removal after the opening is made. The cutter is a sharp tubular cutter, which is gently rotated and advanced through the wall of the aorta, guided by the barbed needle. Once through the wall the cutter and the needle is removed with the retained aorta wall plug, see figure 5.

See figure 5c for the use of the circular cutter system in an aorta.

Another embodiment of aperture forming for smaller primary vessels is to use a ball at the end of the needle so that in does not damage the back wall of the vessel. The ball is still barbed so that when retracted in engages the inside wall of the blood vessel. At this point the cutter is advanced from the outside of the vessel, through the primary vessel wall, creating a controlled size and geometry opening through the wall of a blood vessel. At this point a connector for anastomosis can be advanced into the opening and deployed. The vessel may also be sutured to this opening. See figure 5b.

IV. Delivery and Deployment:

The vein graft is placed onto the connector delivery system as described in section II using the graft transfer sheath. The graft is then secured to the connector by piercing each of the graft attachment fingers through the graft wall. See figure 7 for the vein pierce tool and figure 8 for the connector, graft attachment fingers and loaded graft configuration. Note each delivery tube and its function in figure 9.

The external fingers are then folded back towards the proximal end of the delivery system by the delivery sheath. See figure 10.

A nose cone is then placed over the leading edge of the connector to facilitate placing of the connector into the aorta and to facilitate removal of the delivery system from the aorta after deployment. See figure 11. Note that the cutter apparatus described in section III may be integrated co-axially into the delivery system. The cutter shaft extends through the lumen of the delivery tubes and is rotated independently of the delivery tubes. The circular cutter is advanced through the vessel wall;it is followed by the connector and distal end of the delivery system. The connector is then deployed. The cutter and delivery system is removed together from the attached graft.

Figure 12 shows the deployment of the internal fingers into the primary vessel. This is achieved by advancing tube 2 which un-constrains the internal elastically deformed fingers to 'spring" back to their original preformed shape.

Figure 13 shows the deployment of the external fingers against the outside of the primary vessel wall. This is achieved by retracting tube 5.

Figure 15 is an illustrative view of the final delivery system configuration loaded with a vein graft. Figure 16 shows the internal finger deployment as described in figure 12 within an anatomical context. Note advancement of nose cone. Figure 17 shows the external fingers being deployed against the outside of the aortic wall by retracting the outer sleeve. Figure 19 illustrates the final anastomosis showing an end, inside and outside configuration. Figure 20 is an illustration of a completed coronary artery bypass graft using the mechanical connectors at the aorta.

Summary of Inventions:

I. Connector:

- Attaches a graft to a primary blood vessel
- Unitary device uses internal and external fingers to position graft to primary vessel, attachment fingers to pierce and retain graft to connector, and expansion mean to radially expand and seal graft into opening in primary vessel wall.

II. Delivery:

- Method of delivering a graft to a primary vessel opening and by advancing and retracting co-axial tubes a mechanical connector is deployed, resulting in a completed anastomosis.
- Apparatus for atraumatic removal of distal delivery member such that upon release of connector the nose cone conforms to the delivery shaft eliminating any back edges that may damage the intima of the graft upon removal.

III. Graft Loading:

- A Transfer Sheath to provide a transitionless surface for the handling and transfer of grafts to the Delivery System apparatus.
- Minimizes trauma to the intima of graft

IV. Aperture Forming:

- Circular Cutter apparatus and means to form an opening in a vessel wall that is controlled in size and geometry for the purpose of attaching a graft.

- Graft attachment means may be a mechanical connector or suturing
  The resulting hole is an improvement over prior art punches and scalpels in the it does not damage residual tissue not removed, the size and geometry of the hole is more controlled, the opening is cleaner without rough edges, the hole does not create as much emboli in that the vessel wall is not "crushed" as when punches are used.
- The Circular Cutter may be integrated to the delivery system

V. Delivery and Deployment:

- A series of tubes constrain a mechanical anstomosis device. By advancing a tube and retracting a tube the device is deployed; attaching a graft to a primary vessel.
- A Circular Cutter may be co-axially integrated into the Delivery System to form an aperture (opening) for the advancement of the delivery system into the primary vessel. (primary vessel is the vessel which is the recipient of the graft vessel)
- A Nose Cone may be provided which acts a guide to facilitate advancement of the Delivery System though the wall of a primary vessel.

Unique feature(s) of invention:

- Time to complete anastomosis is reduced
- Hole quality and consistency is improved
- Optimal anastomosis geometry is produced every time
- No side-bite or cross clamping is needed
- No cardiopulmonary bypass pump is needed
- Beating heart compatible
- Diseased vessel compatible
- Outcome performance is technique/skill/experience independent

All of the other patent applications mentioned above are hereby incorporated by reference herein in their entireties.

Aortic Surgical Connector

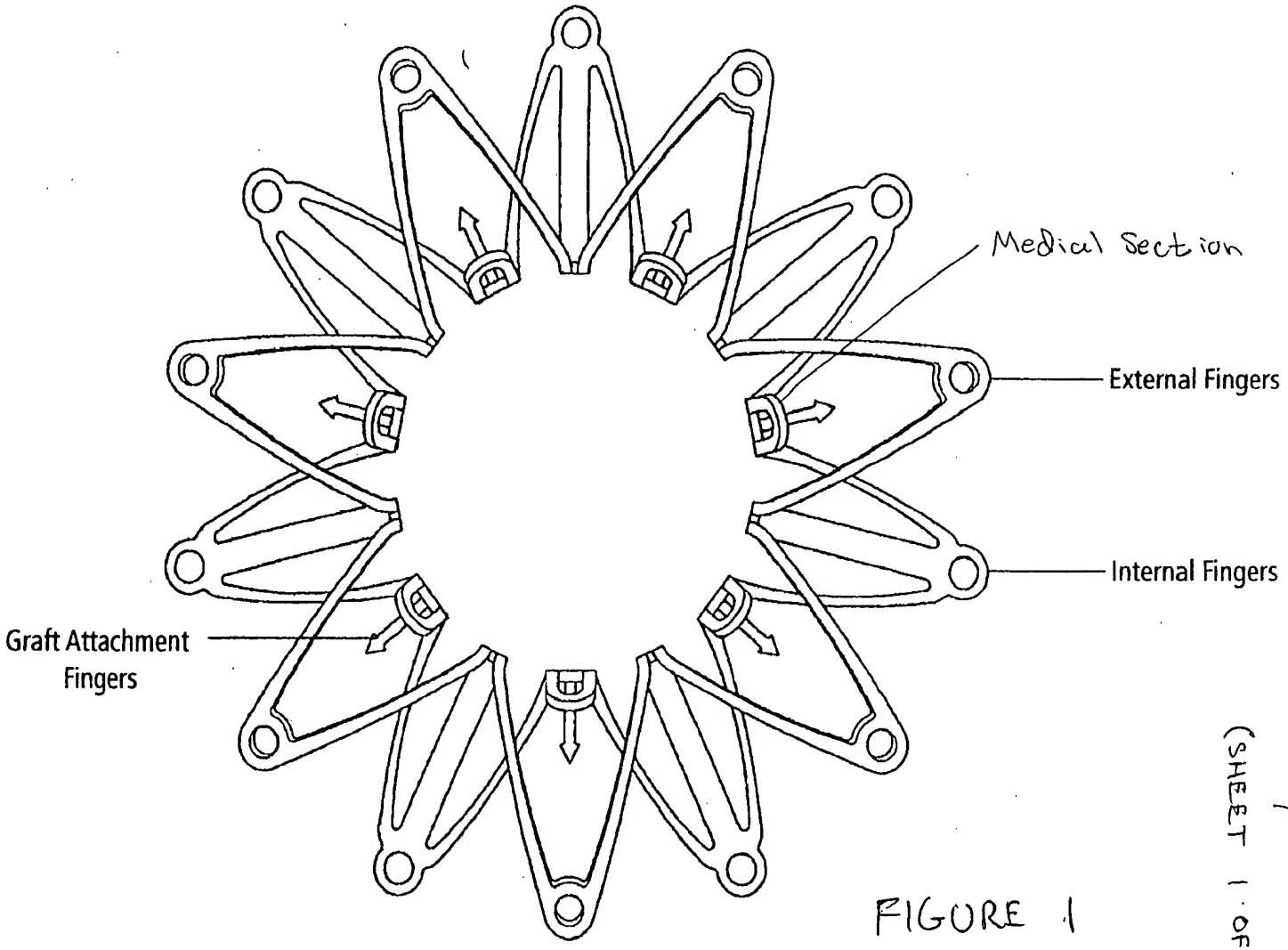

FIGURE 1

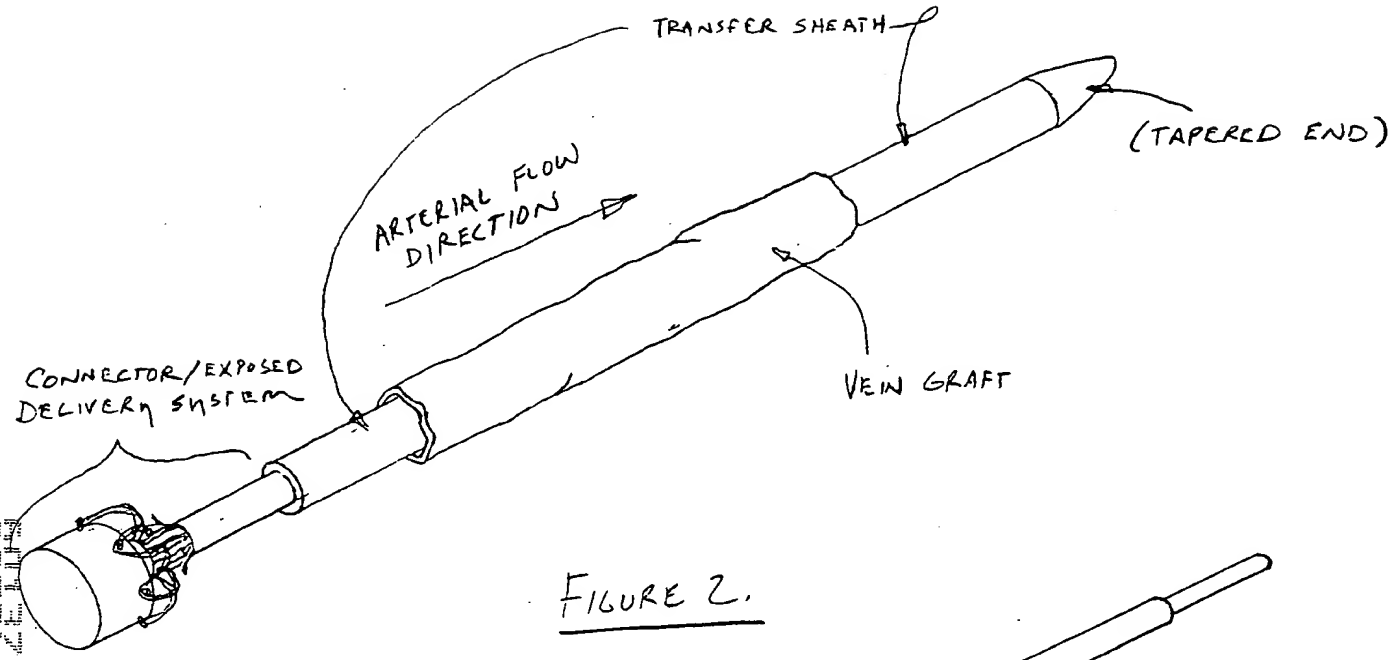

FIGURE 2.

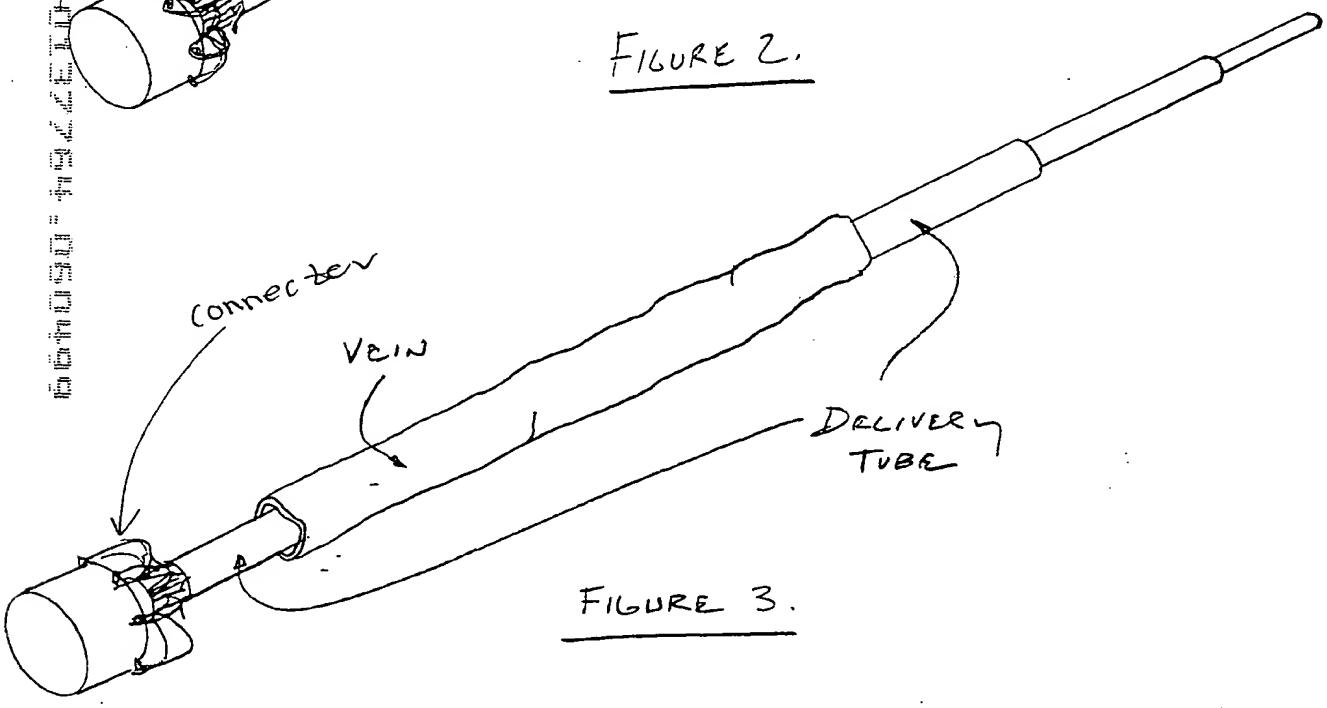

FIGURE 3.

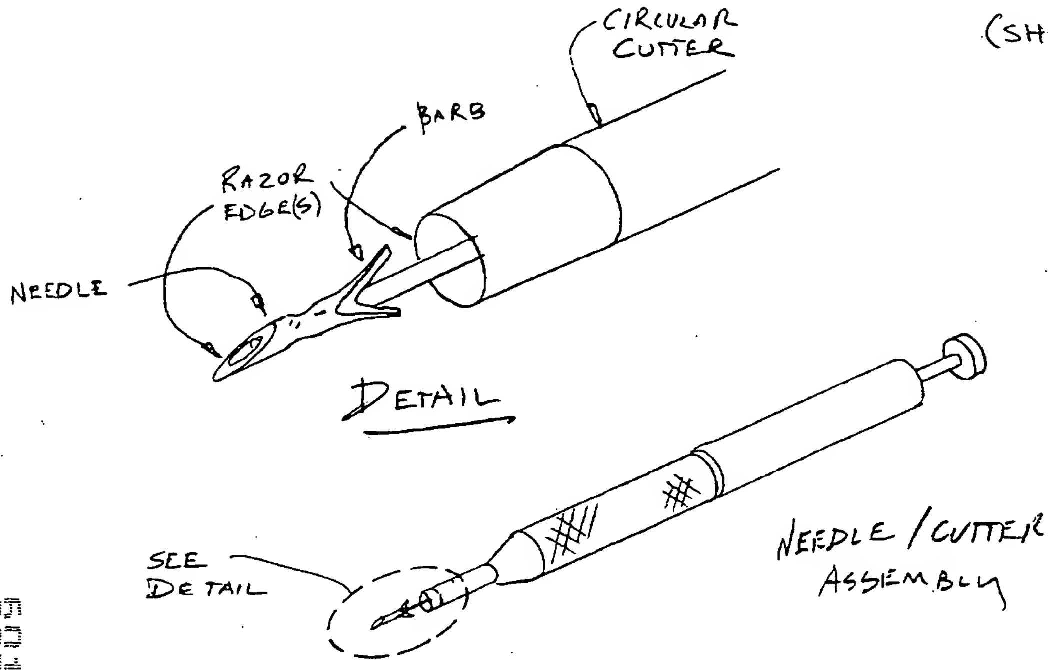

FIGURE 4.

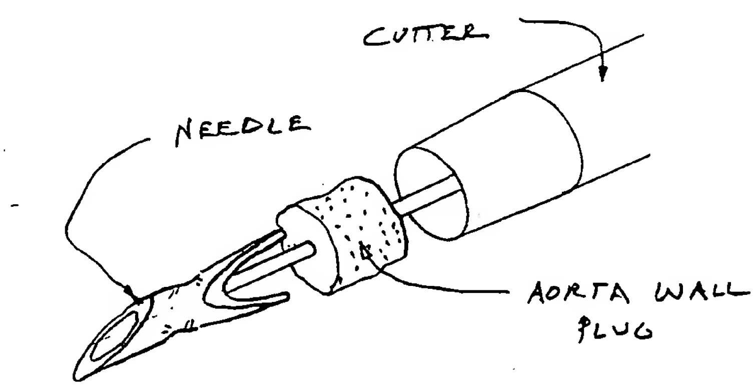

FIGURE 5.

Figure 5b

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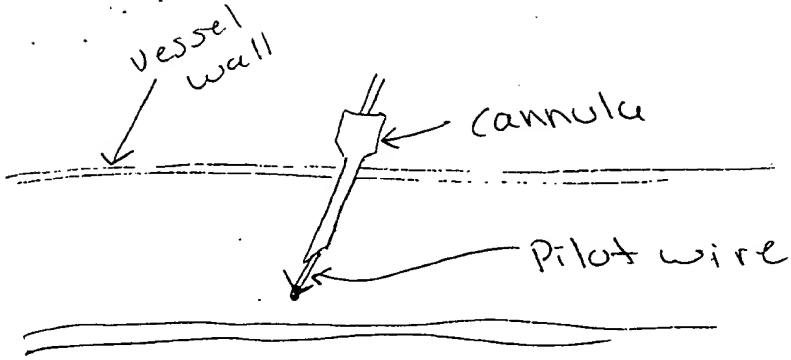
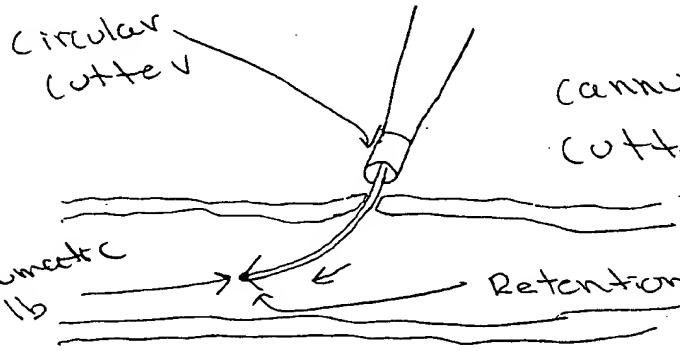
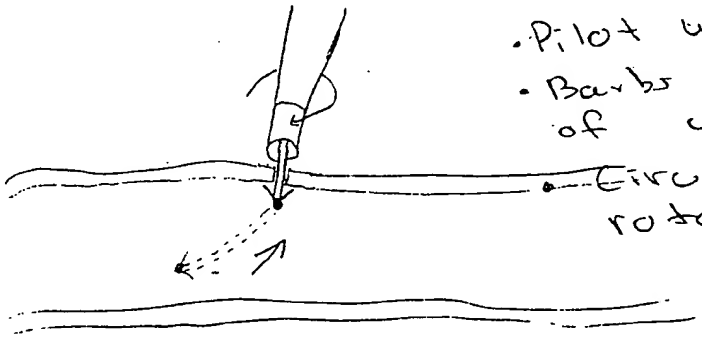


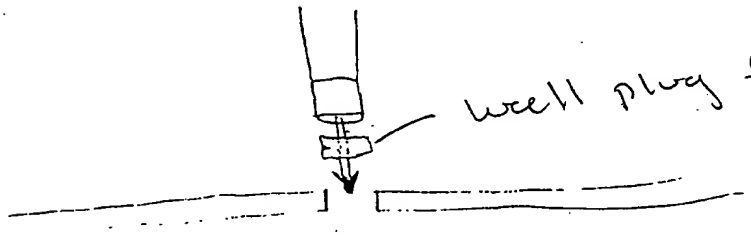


cannula is removed and cutter is inserted over pilot wire



- Pilot wire is retracted
- Barbs engage inside wall of vessel

Circular cutter is rotated and advance



Aperture is formed

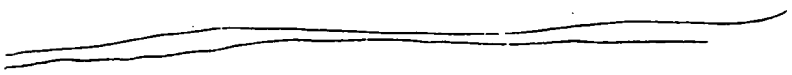
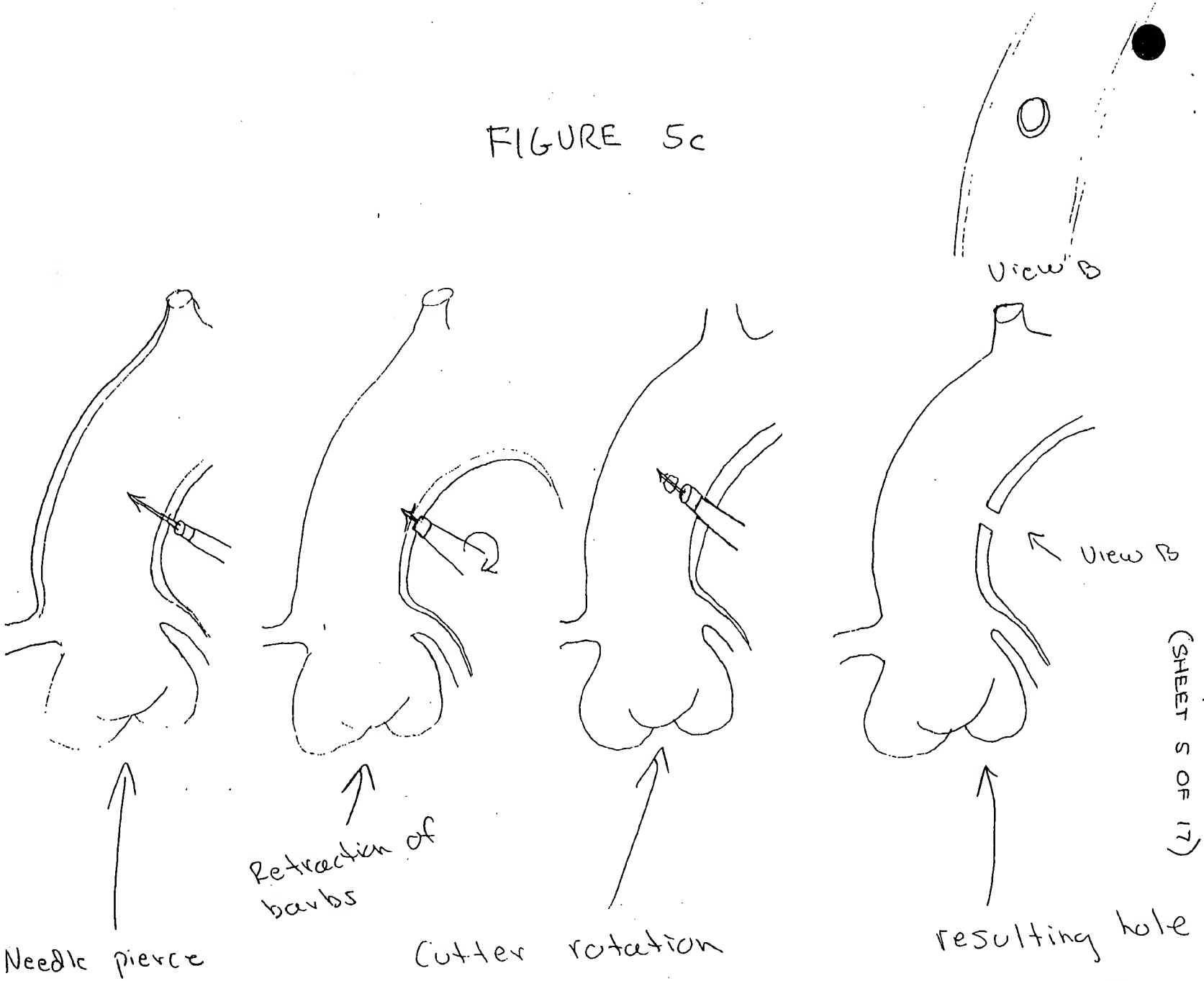
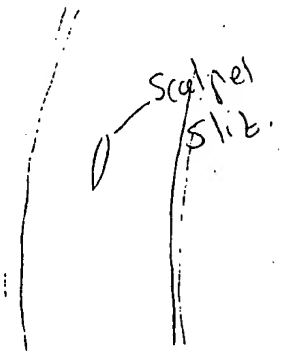


FIGURE 5c

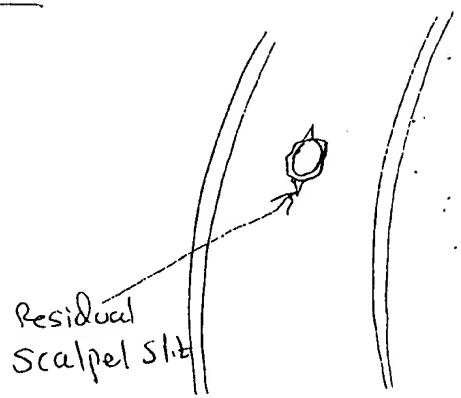


Prior Art Aortic Punch

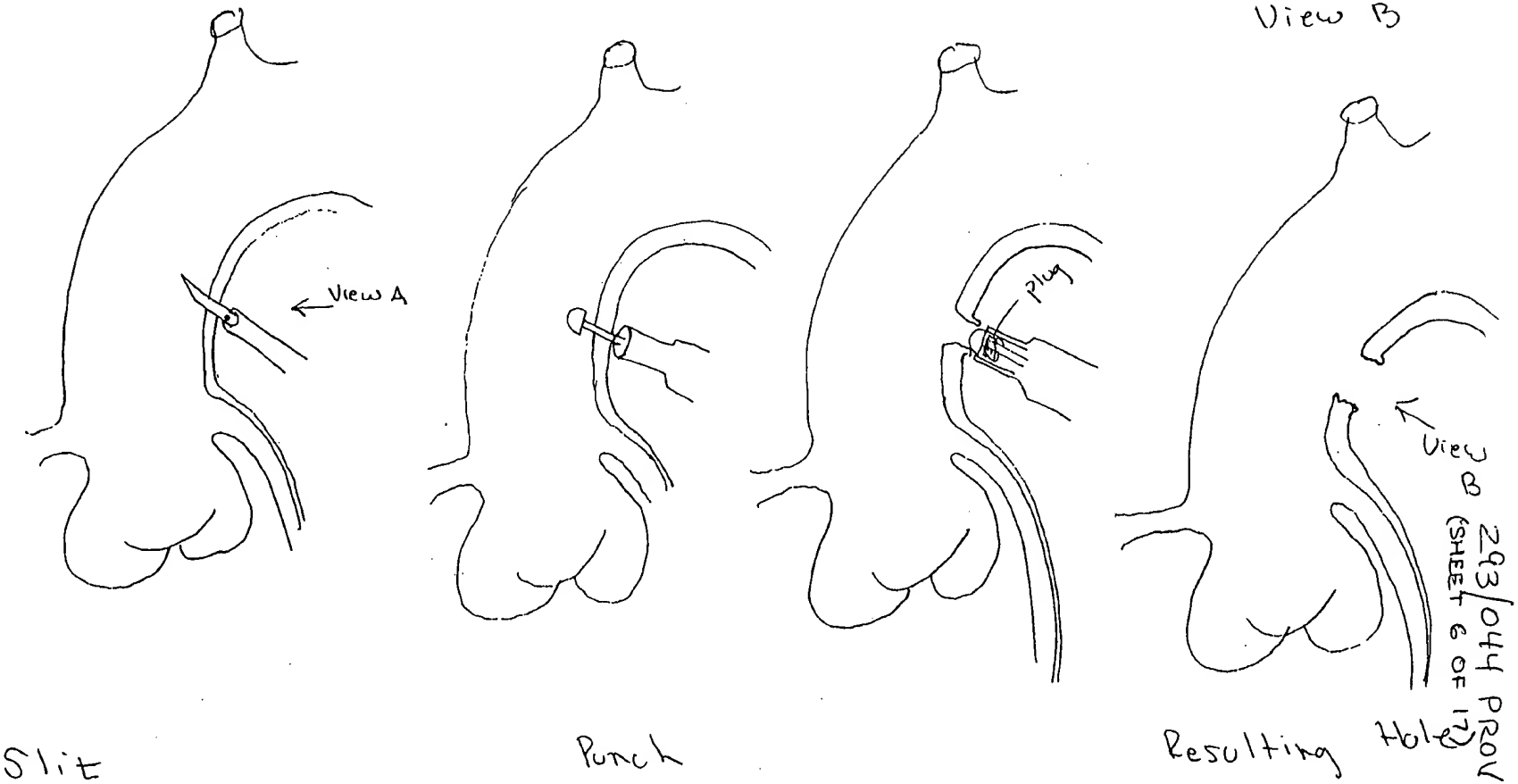
FIGURE 6



View A



View B



Slit w/scalpel

Punch

Resulting Hole

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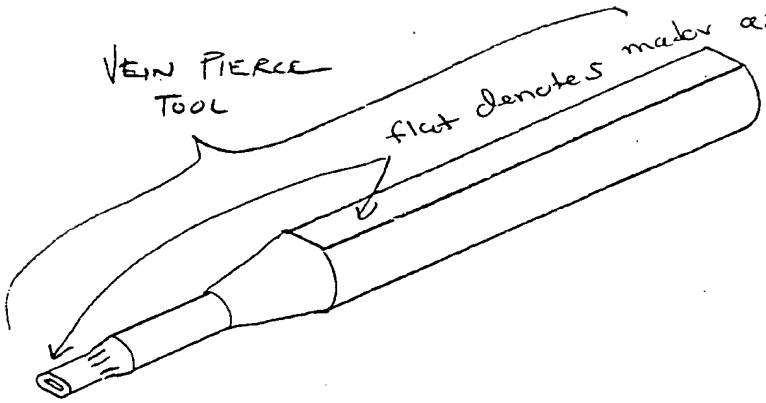

FIGURE 7

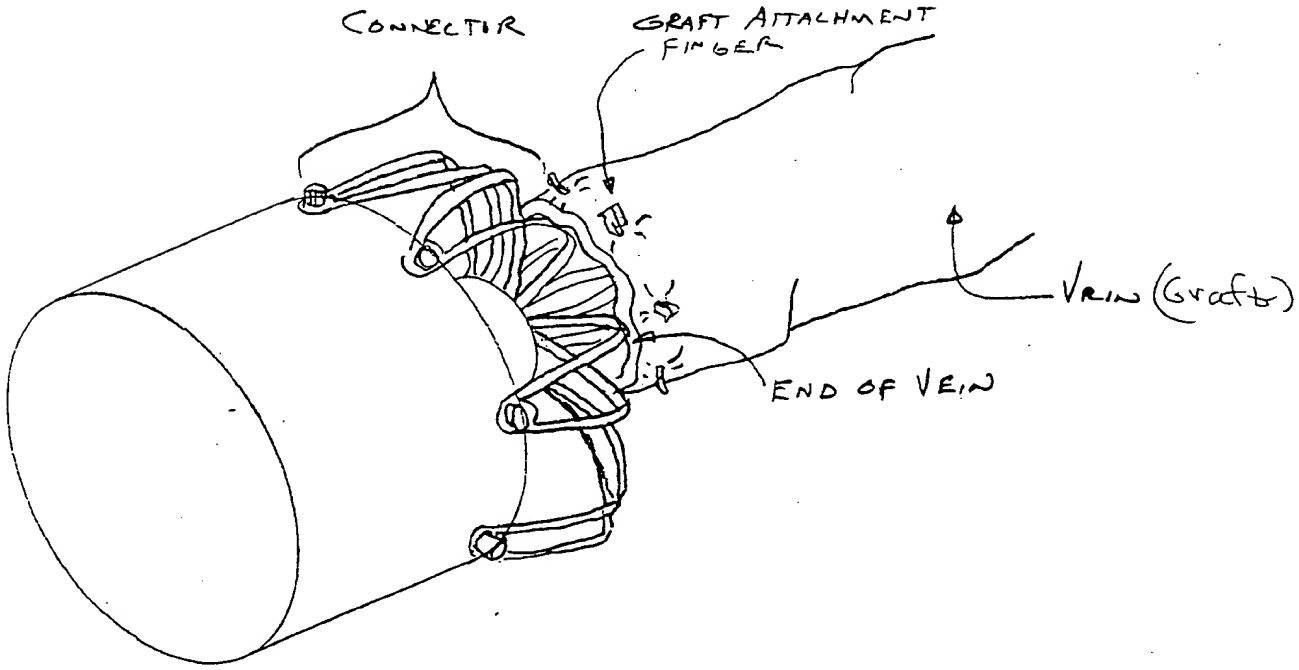

FIGURE 8.

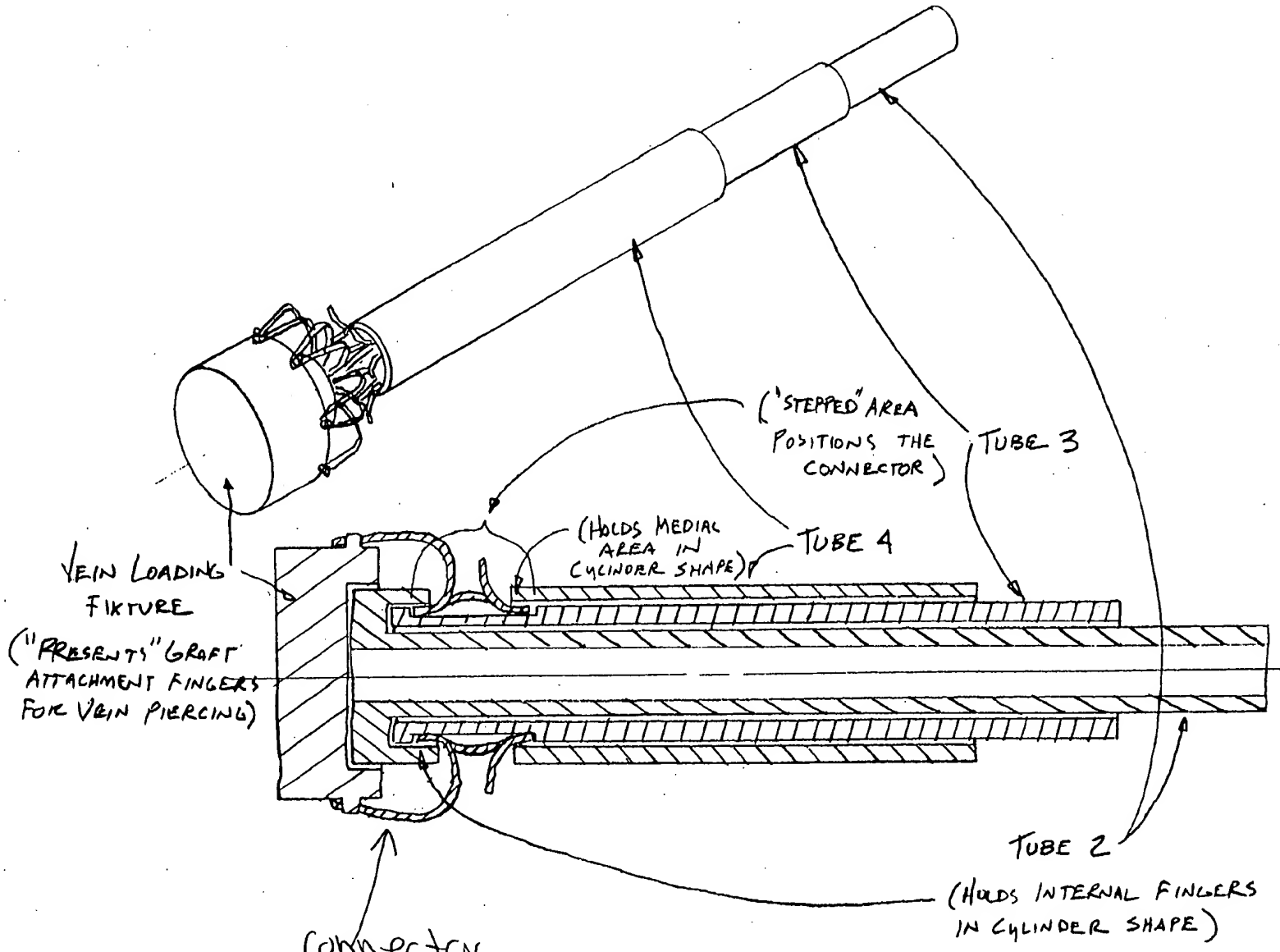

FIGURE 9.

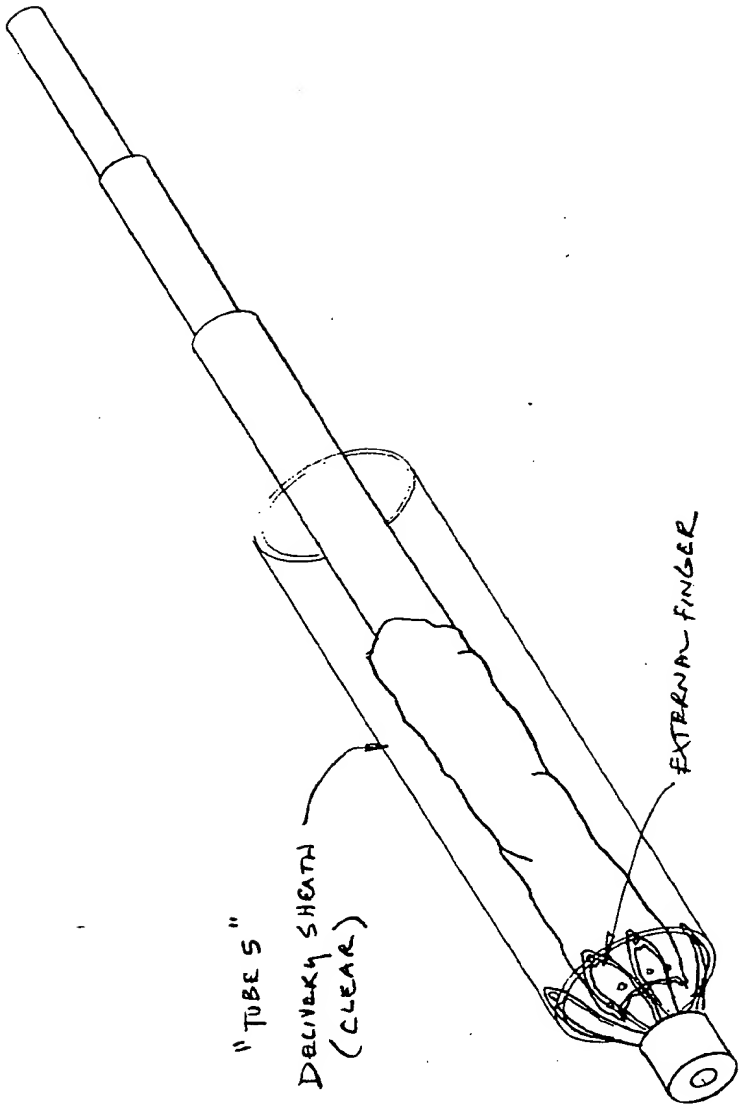

FIGURE 10.

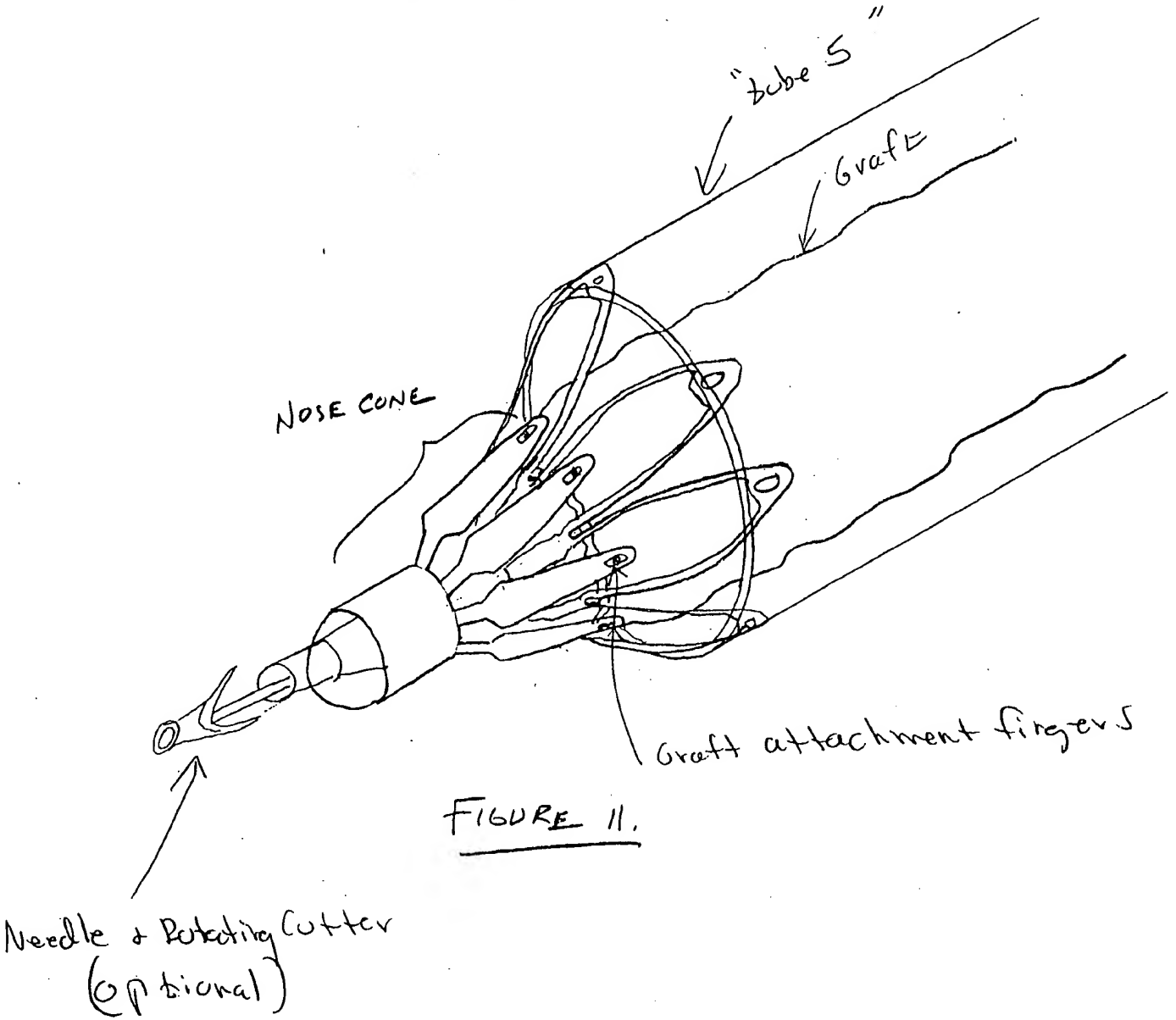

FIGURE 11.

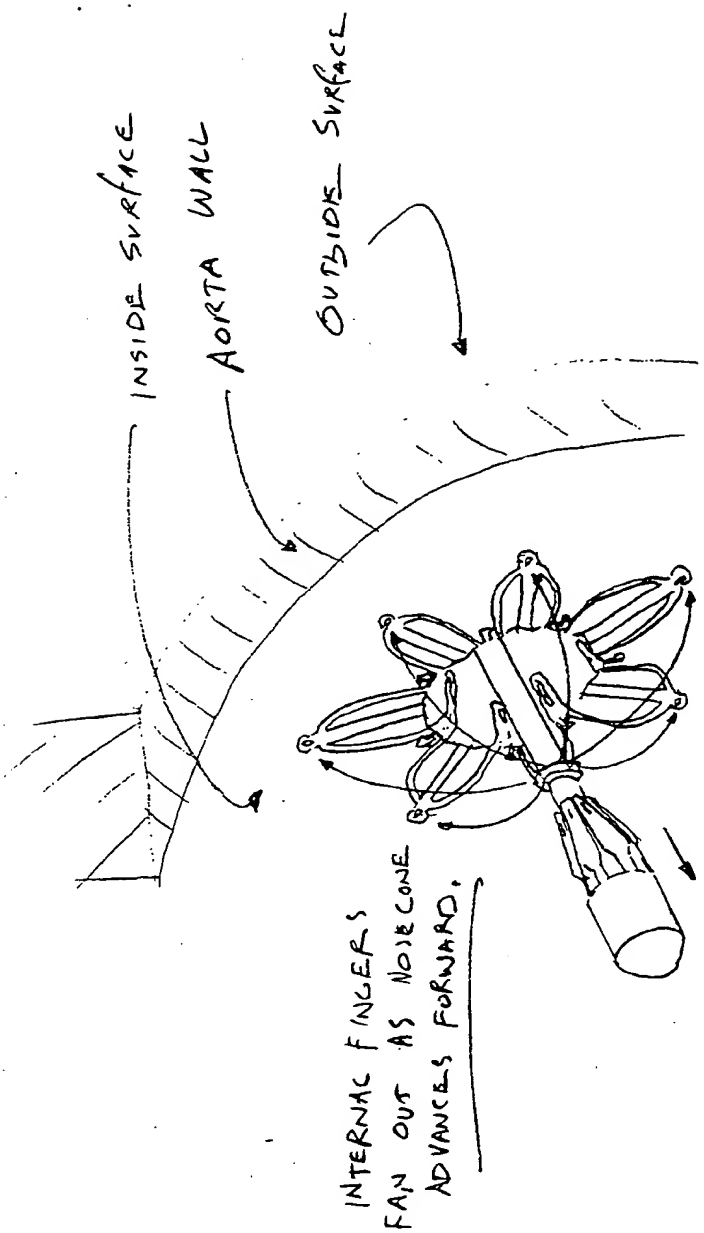
INSIDE SURFACE
AORTA WALL
OUTSIDE SURFACE
INTERNAL FINGERS FAN OUT AS NOSECONE ADVANCES FORWARD.

FIGURE 12.

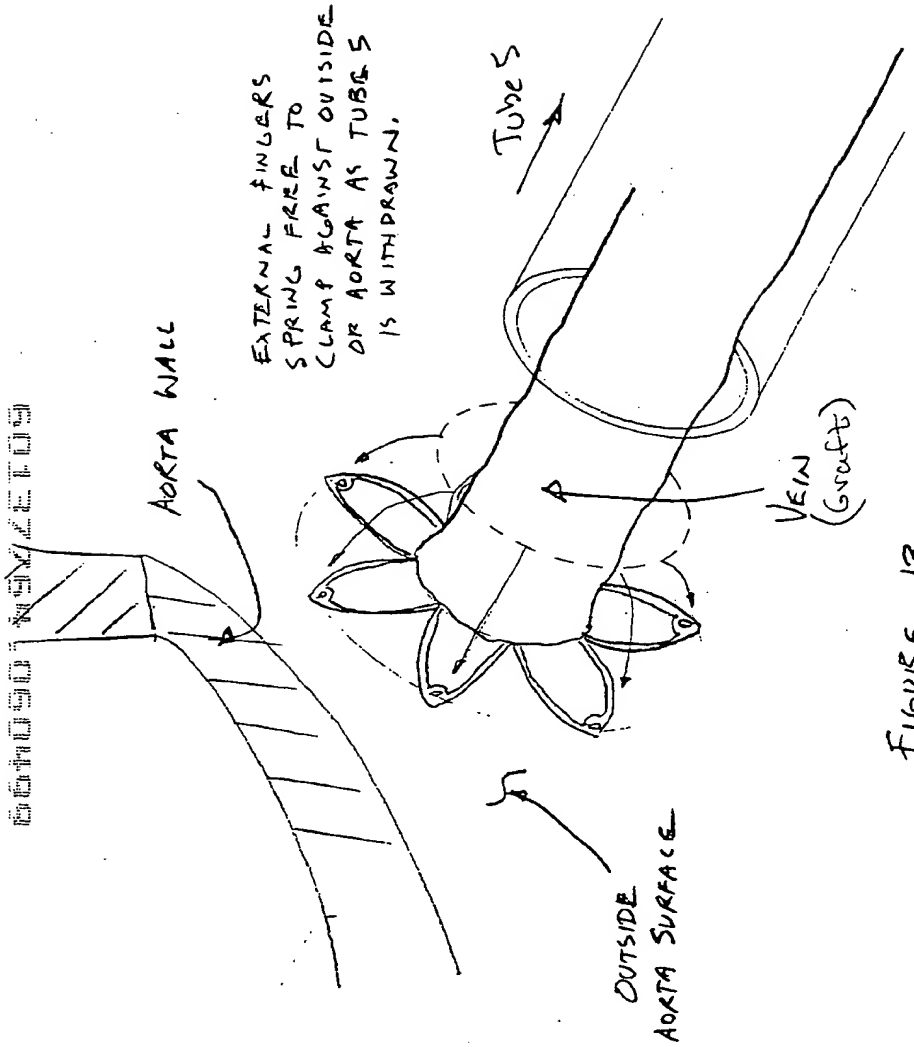
AORTA WALL
EXTERNAL FINGERS SPRING FREE TO CLAMP AGAINST OUTSIDE OF AORTA AS TUBES IS WITHDRAWN.
TUBES
VEIN (Graft)
OUTSIDE AORTA SURFACE

FIGURE 13.

Aortic Surgical Delivery System

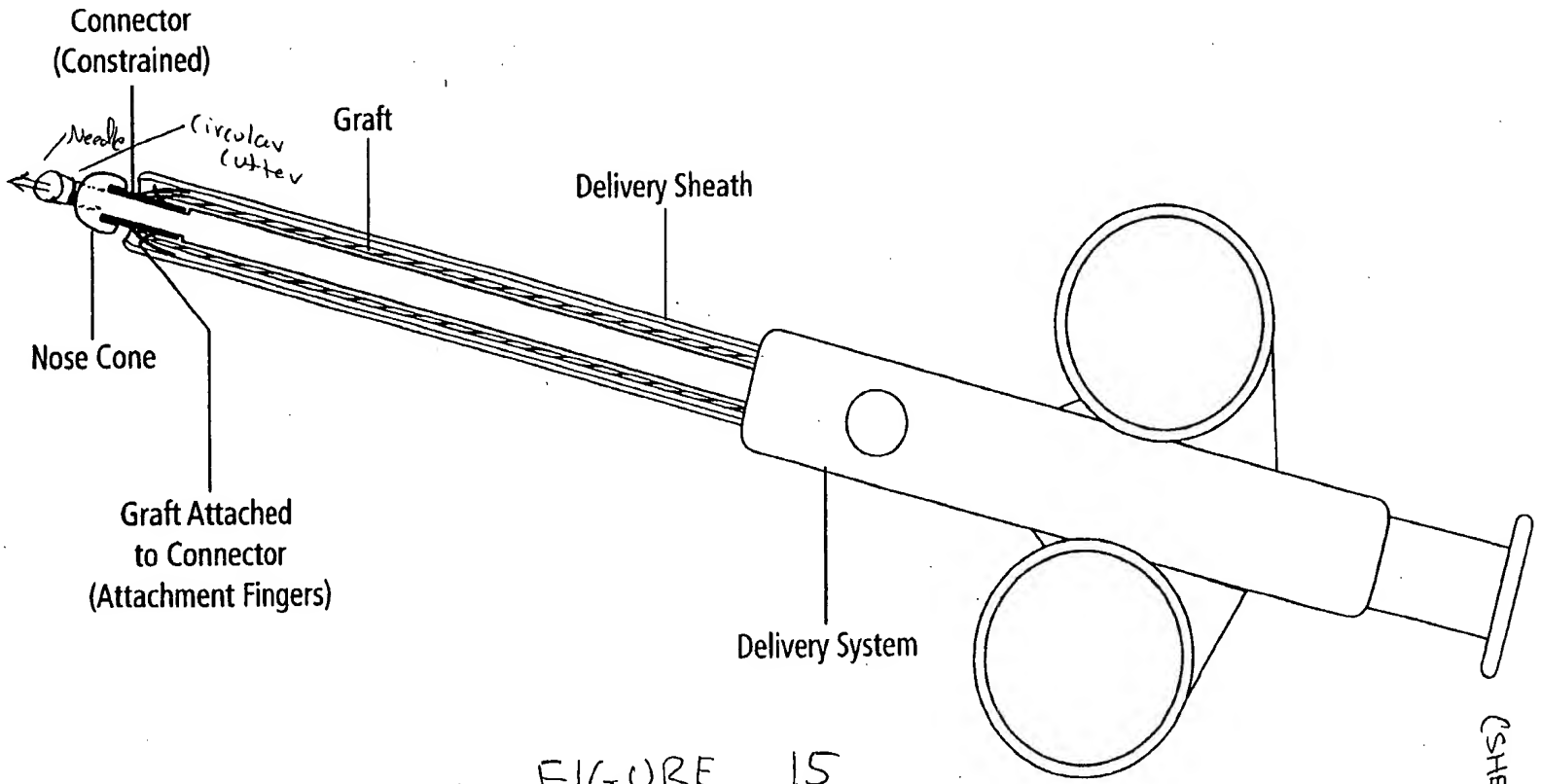

FIGURE 15

Connector Deployment
• Nose Cone Advanced
• Internal Fingers Deployed
Connector
Graft

FIGURE 16

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FIGURE 17

Aortic Surgical Connector

- Anastomosis Complete

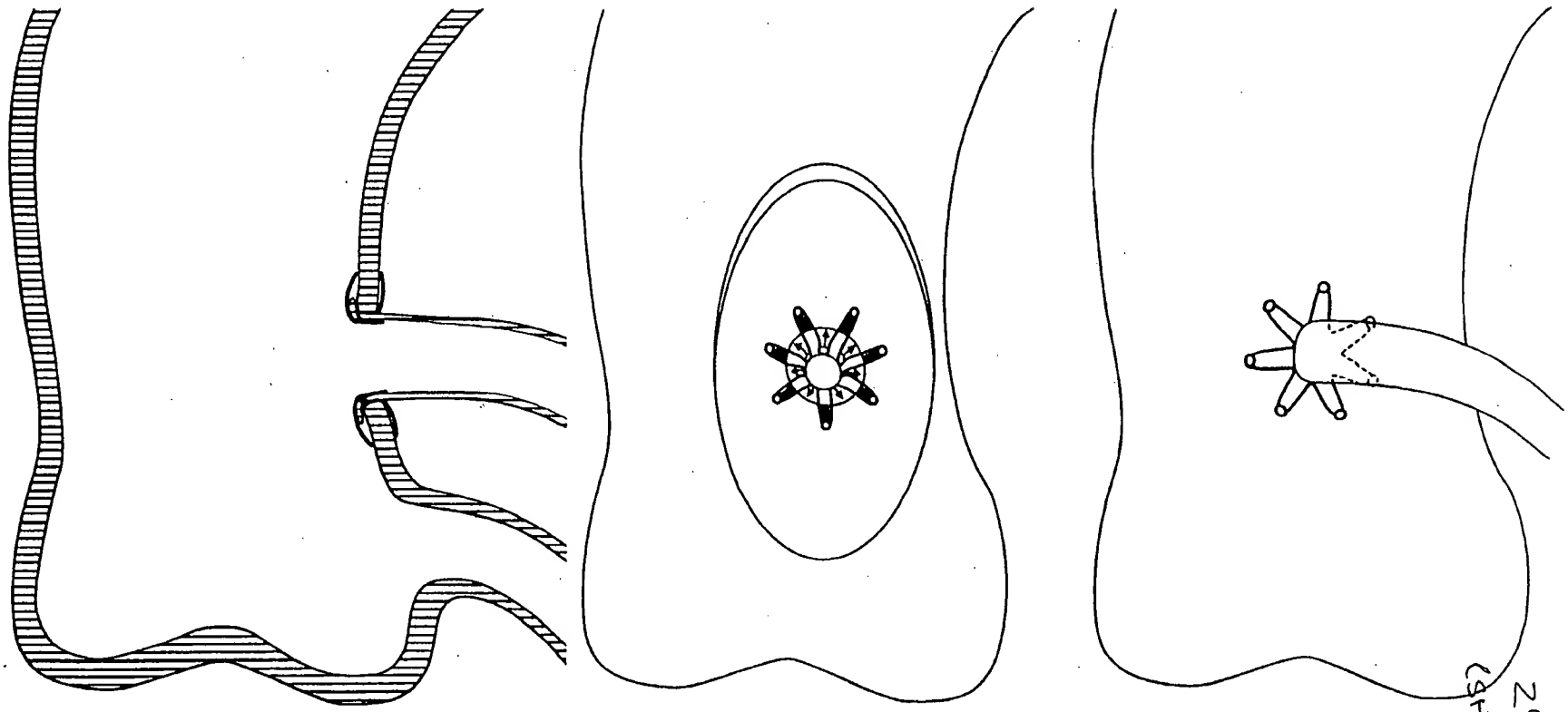

FIGURE 19

FIGURE 20